

100 2005

Food and Drug Administration 555 Winderley Pl., Ste. 200 Maitland, Fl 32751

VIA FEDERAL EXPRESS

Ref: Customs Entry No. 793-0584112-8/001/002

Product: Standard Cheese (100 lbs.)

WARNING LETTER

FLA-99-93

September 23, 1999

Carlos Emilio Calderon, President Don Milos Corporation 9815 N.W. 4th Terrace Miami, Florida 33172-4009

Dear Mr. Calderon:

The Food and Drug Administration (FDA) attempted to examine lbs. of standard cheese offered for entry into the United States by your firm on August 20, 1999, under the above referenced entry number, and found that the shipment was not available for FDA examination. Title 21, Code of Federal Regulations, Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Carlos Emilio Calderon Page 2 September 23, 1999

Your written reply should be addressed to the Food and Drug Administration, Attn: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen

Director, Florida District

Edward R. alkins for